

REMARKS

Method claims 1-10 remain in the application, with independent claims 1 and 6 rewritten in amended form to more specifically define the claimed invention and further distinguish the cited prior art. Apparatus claims 11-17 are cancelled without prejudice to facilitate prosecution and allowance of method claims 1-10.

Reconsideration is respectfully request for claims 1-10 as amended.

Claims 1-10 have been rejected under 35 USC 102(b) as being anticipated by Farace et al. U.S. Patent no. 5,995,863. With reference to claims 1-3, 6-8, and 11-14, the Examiner alleges that Farace et al. disclose a method and apparatus of MRI data acquisition comprising the steps of selecting T₁ and T₂ weigh MR pulse sequence to characterize specific body parts, organ, or tissue where the pulse sequence is used to calculate the selected MR parameter. With regard to claims 4, 5, 9, and 10 the Examiner alleges that Farace et al. disclose that the MR data is presented in image format, which includes either color or black and white.

This rejection is respectfully traversed with respect to method claims 1-10 as presently amended to more specifically define the claimed invention and distinguish the Farace et al. patent. In particular, the claims now specify a method for analyzing tissue and evaluating the quality of repaired tissue based on quantized magnetic resonance data using an MRI measurement acquisition system. In one application for knee analysis, the invention provides a method for analyzing cartilage to determine whether or not it has been injured, and more particularly to analyze joint surfaces that are normally cartilaginous to determine whether or not they have been injured and to present a multicolored spatial representation of the nature of the chondral or chondro-osteal injury, if the joint surface has been injured. If the joint surface has been injured, the method further presents a multicolored spatial representation of the state of tissue repair, if the injured site has gone on to repair and the presentation reveals whether and to what extent this repair is of desired hyaline repair tissue and to what extent any repair that is present is of non-desired fibrous tissue.

As noted in claim 1 as amended, the method includes the steps of :

- a) selecting at least one magnetic resonance parameter to characterize injured tissue,
- b) selecting a suitable pulse sequence to calculate and quantify that selected magnetic resonance parameter,
- c) using the selected pulse sequence, acquiring multiple sets of magnetic resonance signals from the injured tissue

at an unchanged position relative to the measurement acquisition system,

- d) calculating and quantifying the magnetic resonance parameters on a pixel by pixel basis,
- e) determining biological properties of interest of repaired tissue structure by biological means including at least one of histological, biochemical, histochemical, and biomechanical, and
- f) correlating quantitative ranges of the selected magnetic resonance parameters with selected biological properties of interest to determine extent of injury or state of tissue repair.

The claim is now in accord with the Summary of the Invention on page 2 of the specification which states that:

"In accordance with the invention, magnetic resonance parameters are used in the diagnosis of and prognosis for damaged tissue. More particularly, magnetic resonance parameters are quantized for a body part, organ or tissue sample in an area of interest, on a pixel-by-pixel basis. The quantized parameter values of the sample are correlated to quantized parameter values previously determined for healthy tissue structures and for damaged tissue structures and for types of repair tissue.

In a particular application, the invention is directed to the assessment of cartilage damage and cartilage repair. For pixels of a predetermined size, MRI parameters are quantized in areas of interest. These qMRI values are correlated to previously determined parameter values for healthy tissue structures and for damaged tissue structures, and for types of repair tissue.

In specific embodiments, the MRI parameters can be relaxation time (T_1 or T_2), magnetization transfer (MT), or magnetization ratio. Known MRI data acquisition techniques are employed to collect the signal data on a pixel-by-pixel basis for use in calculating the MRI parameter values."

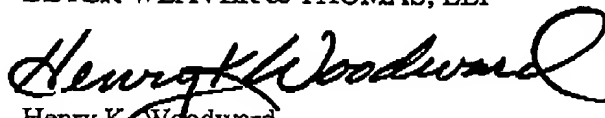
Thus, the invention employs known MRI data acquisition and MRI parameter determination techniques to analyze injured tissue and to evaluate the quality of repaired tissue. This is respectfully submitted to be a new and novel application of known magnetic resonance techniques in the analysis and treatment of injured tissue.

The cited Farace et al. patent is not in any way directed nor applicable to cartilage and bony tissues or joint surfaces, nor is it directed toward determining whether or not such tissues have undergone injury. Nor is the Farace et al patent related to analyzing injured tissue or evaluating the quality or type of repaired tissue, as is the claimed invention. Farace et al. are concerned with planning for hypothermic x treatment of oncological tissue: for example, treating oncological tissue using radiant electromagnetic energy or microwaves. More particularly, Farace et al. are concerned with determining the water/fat content of tissue to be treated since fat tissue plays a special role in hyperthermia due to so-called "hot spots" often occurring inside fat layers and at their interfaces with tissues having a high water content. (See column 4, line 67 - column 5, line 3). In fact, fat tissue, which the Farace patent is principally concerned with, is never present in the joint surface tissue which is the concern of the present invention. And hypothermic treatment, which Farace et al are principally concerned with is never applied to cartilage and bone, which is the principal tissue with which the invention is concerned. Farace et al continue to describe the identification of fat regions by thresholding an image obtained by a subtraction method including the use of a histogram of pixel values whereby distinct distribution curves can be assigned to fat-poor tissue and fat-rich tissues. (column 5, lines 15-35).

Accordingly, it is clear that Farace et al are concerned with possible overheating of tissue which is fat-rich when applying microwave radiant energy in hyperthermic treatments. This is completely unlike the claimed invention in which, for example, the tissues comprising a joint surface are analyzed to determine whether or not there has been an injury; further whether or not the injured tissue has undergone tissue repair; and evaluating the type and quality of the repair tissue. Accordingly, it is respectfully submitted that the claimed method for analyzing injured tissue and evaluating quality of repaired tissue based on quantized magnetic resonance data as defined by claims 1-10 as amended, is neither shown nor suggested by Farace et al.

Since claims 1-10 as amended are patentable under 35 USC 102(b) and 103 over Farace et al., and since apparatus claims 10-17 have been cancelled to expedite prosecution and allowance of the method claims, all as above set forth, it is requested that claims 1-10 as amended be allowed and the case advanced to issue. Should the Examiner have any question or comment regarding the present amended and response which will facilitate allowance of the application, a telephone call to the undersigned attorney is requested.

Respectfully submitted,
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